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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,489	05/25/2000	Ray W. Wood	029318/0596	7761
31049 7590 07/23/2008 Elan Drug Delivery, Inc. c/o Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007-5109			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/577,489

Applicant(s)

WOOD ET AL.

ExaminerJAMES H. ALSTRUM
ACEVEDO**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/3/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-36, 39-40, 42-43, and 51-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-31, 33-36, 39-40, 42-43, and 51-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 28-36, 39-40, 42-43, and 51-63 are pending. Applicants previously cancelled claims 1-27, 41, and 45-50. Applicants have newly cancelled claims 37-38 and 44. Applicants have amended claims 28-32, 42-43, and 51-59. Claims 60-63 are new. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on April 3, 2008 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments. Applicants' amendments have necessitated new rejections of record (i.e. 112, 2nd paragraph rejection of new claims 61-63).

Moot Rejections/objections

All rejections and/or objections of claims 37-38 and 44 cited in the previous office action mailed on December 31, 2007 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 61-63 recite the broad recitation "at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of...", and the claim also recites "at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of..." or "at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of..." which are narrower statements of the range/limitation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-31, 33-36, 39-40, 42-43, and 51-59 **remain rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 24-30 of U.S. Patent No. 6,264,922 (USPN '922) for the reasons of record which are restated below. **New claims 60-63 are appended to this rejection for the reasons of record.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of USPN '922 encompass the cited claims of the instant application. Independent claim 28 of the instant application claims a method of treating a respiratory disease by administering to a mammal's lungs aqueous droplets with a size of less than 10 microns having suspended therein or thereon crystalline therapeutic agent with a submicron particle size, wherein said therapeutic agent has at least one surface modifier on adsorbed on the surface of the crystalline therapeutic agent. Independent claim 24 of USPN '922 claims a method of treating a mammal in need comprising delivering nanoparticles dispersed in liquid droplets having a size of less than 10 microns to the lungs of a mammal, wherein (i) the liquid droplets consist essentially of a liquid, crystalline therapeutic agent, and at least one surface modifier and (ii) said nanoparticles consist essentially of (a) crystalline particles of a therapeutic agent that is poorly soluble in said liquid with an effective average particle size of less than 1,000 nm and (b) about 0.1-90% w/w of at least one surface modifier. Dependent claim

30 of USPN '922 indicates that the liquid may be water. Claim 8 indicates that the inventors of USPN '922 contemplated that the nanoparticles could be beclomethasone dipropionate, which is an art-recognized anti-inflammatory corticosteroid indicated for the treatment of respiratory diseases such as asthma. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 28-31, 33-49, and 51-59 *prima facie* obvious over claims 8 and 24-30 of U.S. Patent No. 6,264,922 (USPN '922).

Response to Arguments

Applicant's arguments filed April 3, 2008 have been fully considered but they are not persuasive. Applicants have traversed this rejection by arguing that the rejection was previously overcome by Applicants' filing of a terminal disclaimer on February 4, 2004 and the previous Examiner's withdrawal of a similar rejection. This is found unpersuasive, because the terminal disclaimer filed on February 4, 2004 is limited to U.S. Patent No. 5,747,001 (see the last full paragraph on page 2 of said terminal disclaimer). The only mention of U.S. Patent No. 6,264,922 in the terminal disclaimer filed on February 4, 2004 is in Applicants' description of the parentage of the instant application on page 1 of said terminal disclaimer. Thus, Applicants' have not disclaimed of U.S. Patent No. 6,264,922 and maintaining the instant rejection is proper at this time.

The rejection of claims 28-31, 33-36, 39-40, 42-43, and 51-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-7 of

copending Application No. 11/592,262 (copending '262) **is moot** because Applicants have abandoned copending '262.

Conclusion

Claims 28-31, 33-36, 39-40, 42-43, and 51-63 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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